



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,841	01/19/99	OLSEN	CIR20013

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HM12/0328

EXAMINER
SCHWADRON, R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/125,841

Applicant(s)  
Olsen et al.

Examiner  
Ron Schwadron, Ph.D.

Group Art Unit  
1644



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-41 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-41 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 36-41 are drawn to methods of preparing lymph node cells, classified in Class 435, subclass 2.

II. Claims 8-15 are drawn to a composition of cells, classified in Class 435, subclass 347.

III. Claims 16-21 are drawn to a method of treatment, classified in Class 424, subclass 93.7.

IV. Claims 22-28 are drawn to methods of preparing helper T cells, classified in Class 435, subclass 2.

V. Claims 29-35 are drawn to helper T cells, classified in Class 435, subclass 375.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions II and V are different products. Invention II is drawn to a mixture of cells, wherein Invention V is drawn to a helper T cell population. Therefore they are novel and unobvious in view of each other and are patentably distinct.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as an immunogen for the production of antibodies which bind said cells.

5. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cells could be made using stimulation in serum containing media.

6. Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cells could made using stimulation in serum containing media.

7. Inventions I,III and IV are different methods that use different ingredients to achieve different goals. Inventions I and IV are drawn to methods of making cells, while invention III is drawn to an in vivo method of treatment. Inventions I and IV are drawn to methods of making different cell populations. Therefore they are novel and unobvious in view of each other and are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-V is not required for any other group from Groups I-V and Groups I-V have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. If applicant elects Group I, the following species election is required.

Claim 37 is generic to a plurality of disclosed patentably distinct species comprising the method of claim 36 wherein the disease is

- a)viral disease
- b)autoimmune disease
- c)bacterial disease.

These diseases are different diseases with different pathologies and disease symptoms.

If applicant elects viral disease, applicant is also required to elect a specific virus from claims 39 and 40 (and specific disease from claim 41 if the elected species causes one of the diseases recited in claim 41).

If applicant elects bacterial disease, applicant is also required to elect a specific bacterial disease from claim 41.

If applicant elects autoimmune disease, applicant is also required to elect a specific autoimmune disease from claim 41.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/125841

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Art Unit 1644



Ron Schwadron, Ph.D.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800 1600

Primary Examiner

Art Unit 1644